

510(k) Summary of Safety and Effectiveness

JUL 18 2012

Proprietary Name: Stryker ReelX STT™ Suture Anchor System Line Extension

Common Name: Fastener, Fixation, Nondegradable, Soft Tissue

Classification Name and Reference: Smooth or threaded metallic bone fixation fastener
21 CFR §888.3040

Proposed Regulatory Class: Class II

Product Codes: MBI: Fastener, Fixation, Nondegradable, Soft Tissue

For Information Contact: Kelly Kucharczyk
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Legally Marketed Devices to Which Substantial Equivalence Is Claimed: K090530 – Spin-Loc Suture Anchor System (legally marketed as Stryker ReelX STT Suture Anchor)
K051219 – Arthrex PushLock
K970896 – DePuy Mitek Panalok Anchor

Date Prepared: July 11, 2012

Purpose

Stryker currently offers a 5.5mm ReelX STT Suture Anchor (cleared as the Spin-Loc Suture Anchor System- K090530). This submission serves to introduce an additional 3.9mm ReelX STT Suture Anchor to the market.

Description

The ReelX STT Suture Anchor System Line Extension (here forth referred to as the 3.9mm ReelX STT Suture Anchor) is an anchor designed to facilitate fixation of soft tissue to bone. The system is comprised of a PEEK polymer and titanium suture anchor preloaded on a disposable inserter. This anchor design allows the surgeon to adjust the tension of the tissue after the anchor has been inserted in bone.

Intended Use

The ReelX STT Suture Anchor System is indicated for use in fixating suture or soft tissue fixation to bone in the shoulder, foot and ankle, knee, and elbow. The anchor is indicated for use in the following procedures.

Indications

The ReelX STT Suture Anchor System is indicated for use in fixating suture or soft tissue fixation to bone in the shoulder, foot and ankle, knee, and elbow. The anchor is indicated for use in the following procedures:

<u>Shoulder:</u>	Rotator Cuff Repair Bankart Repair SLAP Lesion Repair Biceps Tenodesis Acromio-Clavicular Separation Repair Deltoid Repair Capsular Shift/Capsulolabral Reconstruction
<u>Knee:</u>	Medial Collateral Ligament Repair Lateral Collateral Ligament Repair Patellar Tendon Repair Posterior Oblique Ligament Repair Iliotibial Band Tenodesis
<u>Foot and Ankle:</u>	Lateral Stabilization Medial Stabilization Achilles Tendon Repair Hallux Valgus Reconstruction Midfoot Reconstruction Metatarsal Ligament Repair
<u>Elbow:</u>	Biceps Tendon Reattachment

The ReelX STT Suture Anchor is intended for single-use only.

Summary of Technologies

The proposed device is substantially equivalent to other commercially available soft tissue anchors in regard to intended use, design, materials of construct, performance attributes, and operational principles. The following devices are examples of predicate systems: the Spin-Loc Suture Anchor System (marketed as and here forth referred to as the 5.5mm ReelX STT Suture Anchor) and the Arthrex PushLock.

Non-Clinical Testing

Non-clinical ultimate tensile strength testing was performed to characterize both the insertion strength and fixation strength of the 3.9mm ReelX STT Suture Anchor as compared to the predicate devices identified within this premarket notification. The results of this testing indicate that the performance of the 3.9mm ReelX STT Suture Anchor System is substantially equivalent to the predicate devices, and the subject anchors will function within the intended use.

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The 3.9mm ReelX STT Suture Anchor System is substantially equivalent to the predicate devices identified in this premarket notification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Stryker Corporation
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JUL 18 2012

Re: K120824

Trade/Device Name: Stryker ReelX STT™ Suture Anchor System Line Extension
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: June 29, 2012
Received: July 01, 2012

Dear Ms. Kucharczyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

Page 2 - Ms. Kelly Kucharczyk

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120824

Device Name: Stryker ReelX STT™ Suture Anchor System Line Extension

The ReelX STT Suture Anchor System is indicated for use in fixating suture or soft tissue fixation to bone in the shoulder, foot and ankle, knee, and elbow. The anchor is indicated for use in the following procedures:

Shoulder: Rotator Cuff Repair
Bankart Repair
SLAP Lesion Repair
Biceps Tenodesis
Acromio-Clavicular Separation Repair
Deltoid Repair
Capsular Shift/Capsulolabral Reconstruction

Knee: Medial Collateral Ligament Repair
Lateral Collateral Ligament Repair
Patellar Tendon Repair
Posterior Oblique Ligament Repair
Iliotibial Band Tenodesis

Foot and Ankle: Lateral Stabilization
Medial Stabilization
Achilles Tendon Repair
Hallux Valgus Reconstruction
Midfoot Reconstruction
Metatarsal Ligament Repair

Elbow: Biceps Tendon Reattachment

The ReelX STT Suture Anchor System is intended for single-use only.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices